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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,214	01/10/2003	Susan M. Logan	14096.24USWO	1851
23552	7590	11/17/2004	EXAMINER	
MERCHANT & GOULD PC			GEBREYESUS, KAGNEW H	
P.O. BOX 2903			ART UNIT	
MINNEAPOLIS, MN 55402-0903			PAPER NUMBER	
			1652	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/019,214

Applicant(s)

LOGAN ET AL.

Examiner

Kagnew H Gebreyesus

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-70 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

1. Group I, claims 1, 2, 13, 14, 29,30, 41-43, 45, 46, 47, 49-58 in part and claims 4-6, 32-34 in whole, drawn to polynucleotide sequences vectors, host cells, and expression of a *H. pylori* beta 1, 4-galactosyltransferase.
2. Group II, claim(s) 1, 3, 13, 14, 29, 31, 41, 42, 44, 45, 46, 48, 49-58 in part and claims 7-9, 35-37 in whole are drawn to polynucleotide sequences, vectors, host cells, and expression of a *H. pylori* alpha 1, 6-glucosyltransferase.
3. Group III, Claims 1, 3, 13, 14, 29, 31 and 41, 42, 44-46, 48-58 in part and claims 10-12, 38-40 in whole are drawn to polynucleotide sequences, vectors, host cells, and expression a of a *H. pylori* hepatosyltransferase (HP 0479).
4. Group IV, Claims 1, 3, 13, 14, 29, 31 and 41, 42, 44-46, 48-58 in part and claims 10-12, 38-40 in whole are drawn to polynucleotide sequences, vectors, host cells, and expression a of a *H. pylori* hepatosyltransferase (HP 1191).

5. Group V claims 15-16, 27 and 28, 67, 68 in part and 18-20, in whole are drawn to a beta 1, 4-galactosyltransferase.
6. Group VI claims 15, 17, 27 and 28, 67, 69 in part and 21-23 in whole are drawn to an alpha 1, 6-glucosyltransferase.
7. Group VII claims 15, 17, 27 and 28 in part and 24-26 in whole are drawn to a hepatosyltransferase enzyme (HP 0479).
8. Group VIII claims 15, 17, 27 and 28 in part and 24-26 in whole are drawn to a hepatosyltransferase II enzyme (HP 1191).
9. Group IX, claims 59-62 in part are drawn to mutant strain of *H. pylori* carrying a mutation on the beta-1, 4-galactosyltransferase (HP0826) gene involved in the biosynthesis of *Helicobacter pylori* LPS.
10. Group X, claims 59-62 in part are drawn to mutant strain of *H. pylori* carrying a mutation on the glucosyltransferase (HP0159) gene involved in the biosynthesis of *Helicobacter pylori* LPS.
11. Group XI, claims 59-62 in part are drawn to mutant strain of *H. pylori* carrying a mutation on the hepatosyltransferase gene (HP 0479) involved in the biosynthesis of *Helicobacter pylori* LPS.
12. Group XII, claims 59-62 in part are drawn to mutant strain of *H. pylori* carrying a mutation on the ADP-Hepatoase-LPS hepatosyltransferase II gene (HP1191) involved in the biosynthesis of *Helicobacter pylori* LPS.
13. Group XIII, claims 63-66, 70 in part are drawn to a vaccine composition comprising an antigen or a live attenuated vaccine derived from a mutant strain of *H. pylori* having a mutated beta-1, 4-galactosyltransferase.

14. Group XIV, claims 63-66, 70 in part are drawn to a vaccine composition comprising an antigen or a live attenuated vaccine derived from a mutant strain of *H. pylori* having a mutated glucosyltransferase.
15. Group XV, claims 63-66, 70 in part are drawn to a vaccine composition comprising an antigen or a live attenuated vaccine derived from a mutant strain of *H. pylori* having a mutated heptosyltransferase (HP 0479).
16. Group XVI, claims 63-66, 70 in part are drawn to a vaccine composition comprising an antigen or a live attenuated vaccine derived from a mutant strain of *H. pylori* having a mutated ADP-Hepatoase-LPS heptosyltransferase II (HP 1191).

\* Claim 70 is unclear since no reaction mixture is claimed in claim 66 which it refers to.

Therefore the claim was read as “a vaccine composition or a live attenuated vaccine according to claim 66, wherein the bacterial lipopolysaccharides is a mimetic of a *Helicobacter* lipopolysaccharide”.

The technical features linking the inventions of group I-XIX is summarized as follows:

- 1) The use of a mutated polynucleotide sequences of at least one glycosyltransferase gene (from Group I-III) that code for the corresponding proteins (of Group IV-VI) introduced in *H. pylori*, thus generating a mutant strain of *H. pylori* with an mutant LPS which is subsequently used either as a live vaccine formulation or the LPS (at least partially purified) derived from a mutant strain used as an antigen in a vaccine formulation.

2) The use of a mutated glycosyltransferase produced in a eukaryotic or prokaryotic cell in a reaction mixture for enzymatic synthesis of a *H. pylori* lipopolysaccharide mimetic is disclosed. However, SEQ ID NO: 1 corresponding to beta 1, 4-galactosyltransferase is 100% identical to region 1551-2372 of *Helicobacter pylori* genomic sequence (Tombs et al. 1997). Tombs et al. annotate this region (HP0826) as a lipooligosaccharide epitope biosynthesis protein showing similarity to lex2B gene encoding a glycosyltransferase from *Haemophilus influenzae*. WO 99/40205 also describes a protein with a beta1, 4-galactosyltransferase activity from *Helicobacter pylori* and a process for producing the same. In addition, Tombs et al., also annotate HP0159, HP0679 and HP1191 as lipopolysaccharides 1,2-glucosyltransferase, a lipopolysaccharides biosynthesis protein and ADP-heptose-lps heptosyltransferase respectively from *Helicobacter pylori*. In addition Faver et al. (US 6,613,321 B1 with priority of 6/15/98) teach live attenuated gram-negative vaccine carrier strains used in the delivery of attenuated gram-negative bacteria expressing heterologous O-antigens from gram-negative pathogens. Therefore the technical features linking Groups I-XIX do not constitute a special technical feature as defined by PCT rule 13.2 as the technical features do not define a contribution over the prior art.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a none elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (B) and by the fee required under 37 CFR 1.17 (i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagnew H Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Kagnew Gebreyesus PhD.*  
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1600